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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,571	07/13/2000	Paul Harris	5951.010-US	4949

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EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/615,571	HARRIS ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *100,102-107,109-112,114-117 and 119-128* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *125-128* is/are allowed.

6)☒ Claim(s) *100,102-104,109-111,114,115,117 and 119-124* is/are rejected.

7)☒ Claim(s) *105-107,112 and 116* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/04 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 100, 102-104, 109-111, 114-115, and 120-124 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record applied to claims 71-75, 79-82, 84-86, and 91-95, respectively, in the Office action of 12/7/01.

Applicant's arguments filed 11/26/04 have been fully considered but they are not persuasive. Applicant argues that the specification complies with the written description requirement because it identifies three structural features common to members of the generic

invention: percent amino acid sequence identity of the amino acid sequences encoded by the nucleic acids; percent nucleotide sequence identity of the nucleic acids; and nucleic acid hybridization. Applicant argues that these structural features are correlated to function of protein encoded by the nucleic acid, and points to the Berka declaration as supporting evidence.

However, the structural features on which Applicant relies do not distinguish between nucleic acids that are claimed, i.e. those which meet the structural limitations of the claims and encode a phospholipase B, from those which are not claimed, i.e. those which meet the structural limitations of the claims but do not encode a phospholipase B. It must be kept in mind that the claims are not limited to nucleic acids isolated from nature or nucleic acids encoding phospholipase B enzymes found in nature. The claims also embrace man-made variants of SEQ ID NO: 1 or variants of nucleic acids that encode SEQ ID NO: 2 that encode polypeptides differing from SEQ ID NO: 2. Amino acids changes can be made in SEQ ID NO: 2 that will render the polypeptide inactive as a phospholipase B. Presumably, changes could also be made that would not eliminate phospholipase B activity. The specification does not teach characteristics of the proteins encoded by each class, active vs. inactive, that would distinguish them from one another, or allow one of skill in the art to envision those readable on the claims.

Applicant's arguments on pages 2-5 and paragraph 3 of the Berka declaration are directed in part to evidence that shows a correlation between amino acid sequence (primary structure) and protein structure (tertiary structure) of naturally-occurring proteins (the two Bork references and the Chothia reference provided with the declaration). However, Bork (1994) at page 397 teaches that whether one can predict protein function based upon amino acid sequence homology to a protein of known function depends upon the data at hand. Bork cautions that even in simple

cases where there is strong sequence similarity to a protein of known function, sequence variation can have diverse consequences. For example, highly similar proteins can have completely different functions and the substrate specificity of clearly homologous proteins can be changed completely. Bork (1998) teaches that molecular characteristics such as enzymatic activity, interaction partners, and pathway context can be predicted from sequence comparisons only qualitatively, and most of the functional features of proteins (with no known function) cannot be predicted from sequence data. Bork (1998) lists other pitfalls in predicting protein function from sequence comparisons (page 707, col. 2 through page 710). The Berka declaration then provides evidence that for many naturally-occurring metabolic enzymes, and the nucleic acids that encode them, which share sequence similarity of 90% or higher, the proteins have the same enzymatic activity.

With respect to Wilson (provided with the declaration), Wilson does not address whether the function of proteins can be predicted by sequence comparison to proteins of known function as asserted in Applicant's reply and in the declaration, but whether the function of putative protein folds (SCOP domains, page 242; page 245, col. 2) found within a new protein can be predicted by sequence comparison to proteins of known function having a that protein fold. Also, as indicated on page 242, col. 2, when Wilson speaks of two proteins having the "same precise function," he does not mean that the proteins actually perform the same enzymatic reaction on the same substrates to produce the same products. For example, as defined by Wilson, alcohol dehydrogenase and homoserine dehydrogenase have the "same precise function", but these enzymes do not act on the same substrates or produce the same products. By Wilson's definition, cholinesterase (EC 3.1.1.8) and phospholipase B, i.e. lysophospholipase, (EC 3.1.1.5) share the

same precise function, i.e. they hydrolyze carboxylic esters. These enzymes act on different substrates, a choline ester and a phospholipid, respectively. Phospholipase C (EC 3.1.4.3) shares "general similarity" with phospholipase B since these two enzymes share at least two, but not three (required for "same precise function"), ENZYME numbers in common (see Fig. 7, which shows carboxylic ester hydrolases, EC 3.1.1). (Also see the Enzyme Commission (EC) web site at www.chem.qmul.ac.uk/iubmb/enzyme/EC3/1/ for classification of esterases; www.chem.qmul.ac.uk/iubmb/enzyme/EC3/1/1/ for classification of carboxylic ester hydrolases; and www.chem.qmul.ac.uk/iubmb/enzyme/EC3/1/3/ for classification of phosphoric diester hydrolases.). The issue here is not whether a claimed nucleic acid would encode a carboxylic esterase, but phospholipase B specifically. Phospholipase C, to which SEQ ID NO: 2 had the highest similarity, shares only general similarity with phospholipase B, i.e. it is an esterase, and not the "same precise function" in Wilson's system. If one had predicted the function of SEQ ID NO: 2 from sequence data available at the time the application was filed, one might have predicted it was a phospholipase C, or at least a phosphoric diester hydrolase, and one would have been wrong.

Thus, Applicant and Dr. Berka are overstating the meaning of the prior art evidence discussed. However, the Office agrees (and has never disagreed) with the argument that if a naturally-occurring enzyme or naturally-occurring enzyme coding nucleotide sequence shares 90% sequence identity with SEQ ID NO: 2 or 1, respectively, or if a naturally-occurring enzyme coding nucleotide sequence hybridizes under medium-high stringency conditions to SEQ ID NO: 1, then more likely than not, the enzyme would be a phospholipase B. However, the issue is

whether the specification adequately describes such naturally occurring sequences and whether Applicant was in possession of such.

The specification fails to provide an adequate written description of the claimed genus of nucleic acid sequences for two reasons relevant to naturally occurring sequences. First, the claims are not limited to naturally-occurring nucleic acids or nucleic acids encoding a naturally-occurring phospholipase B. As indicated in Smith (provided with the declaration), evolution of a protein sequence is likely to occur by single-amino acid changes, and natural-selection eliminates those individuals carrying non-functional or deleterious changes. Consequently, those nucleic acid sequences or proteins found in nature have already been "screened" by nature to be functional. One can reasonably predict that a newly-discovered enzyme, or its coding sequence, found in nature has the same activity as a known enzyme if their sequence similarity is sufficiently high, e.g. 90%, because one can assume that the new enzyme is active, even if one is not absolutely certain that activity of the new enzyme is the same as the structurally related enzyme. Unlike naturally-occurring proteins, however, one cannot predict solely from the amino acid sequence whether a given man-made change in the amino acid sequence would inactivate the enzyme or not. That has to be determined by man by assaying the activity of the polypeptide encoded, analogous to natural selection in nature. The specification does not teach how to envision those changes in SEQ ID NO: 2 that would not eliminate phospholipase B activity.

Second, the only naturally-occurring nucleotide and amino acid sequences disclosed in the specification are SEQ ID NOs: 1 and 2. There is no evidence of record that Applicant was in possession of any other naturally-occurring sequences. A search of the prior art failed to reveal any nucleic acid sequence that came anywhere near to meeting the physical limitations recited in

the claims. While one may be able to use SEQ ID NO: 1 as a hybridization probe to screen nucleic acids isolated from *Aspergillus oryzae* and other organisms, one cannot envision from the specification what nucleic acid sequence would be found. The fact that Applicant is suggesting that one of skill in the art do so is tacit admission that Applicant was not in possession of what one might find. If one were to make a single nucleotide change in SEQ ID NO: 1 or a single amino acid change in SEQ ID NO: 2, one would not know whether or not such a sequence exists in nature until either an identical sequence is isolated from nature or after all possible structurally-related sequences had been isolated from nature and none found to be identical to the variant sequence. If one were to be presented with a sequence that differed from SEQ ID NO: 1 or SEQ ID NO: 2 within the bounds of the claims, one would be unable to determine from the specification whether it was naturally-occurring. Since the specification does not provide any evidence that Applicant was in possession of other naturally-occurring nucleic acid sequences than SEQ ID NO: 1 or nucleic acid sequences encoding other naturally-occurring phospholipase B enzymes than that of SEQ ID NO: 2, and the specification fails to provide characteristics allowing one to envision the other naturally-occurring nucleic acid sequences or nucleic acid sequences encoding other naturally-occurring phospholipase B enzymes, the written description requirement is not met for a subgenus (as yet unclaimed) of naturally-occurring variants readable on the claims. Whether or not the specification would enable one to isolate such sequences from nature using SEQ ID NO: 1 as a hybridization probe is not relevant to the written description inquiry, see *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398, 1405 (CA FC, 1997)).

With respect to Applicant's arguments in the first full paragraph of page 5, and paragraph 4 of the Berka declaration, the contention by the Office that one cannot envision which nucleic acid sequence that meets the structural limitations of the claims also encodes a phospholipase B is directed to nucleic acid sequences made by man by mutagenesis, not those made by isolating them from nature. Wilson only addresses structure-function correlations between domains in natural proteins, and says nothing about the likely function of man-made derivatives. Furthermore, at the time the invention was made, there were no naturally-occurring sequences that met the claim limitations disclosed either in the specification or prior art to which one could compare SEQ ID NOs: 1 or 2.

With respect to Applicant's arguments on pages 5-6, and paragraph 5 of the Berka declaration, these arguments and evidence are directed to non-natural sequences that meet the claim limitations. Guo, which was provided with the declaration, discloses that proteins appear to be more tolerant of single amino acid substitutions than was previously thought. Specifically, that about one third of randomly introduced single amino acid changes would inactivate a generic protein. Applicant argues that this contradicts "the Office's contention that random (even conservative) changes in a protein in the absence of structural information would adversely affect folding and/or activity" (emphasis added).

In response, the Office contended "it is known in the art that even conservative amino acid substitutions can adversely affect proper folding and biological activity if amino acids that are critical for such functions are substituted, and the relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable" (emphasis added), citing Ngo. Guo further supports this contention, see Table 2 where the *x*-factor for

amino acids in the active site region was much higher than for the protein overall. The specification does not identify those regions or amino acids of SEQ ID NO: 2 involved in proper folding and biological activity.

Furthermore, Guo teaches that one third of single amino acid substitutions fully inactivate a protein, and that increasing the number of amino acid substitutions additively increases the probability of inactivating the protein, at least for a few amino acid changes (see Table 1; page 9207, col. 1). For example, an average of 6 amino acid changes (i.e. 98% identical to the original 299 amino acid protein) inactivated 90% of the polypeptides. In contrast to the low level of substitution analyzed by Guo, the claims allow at minimum changing 44 amino acids (claim 100, part (a)) and substantially more (e.g. claim 100, parts (b) and (c)). A nucleic acid sequence that is 90% identical to nucleotides 568-2045 of SEQ ID NO: 1 (claim 100, part b) could encode a protein that is less than 70% identical to SEQ ID NO: 2 even if all the changes were substitutions that did not create a stop codon. If all of the permitted nucleotide changes (147) are each made in non-wobble positions of different codons, 147 amino acids would be changed in the encoded polypeptide of 444 amino acids, i.e. only 66% of the amino acids would be identical. Guo does not address this level of amino acid substitutions, or how the *x*-factor might be used to estimate the fraction of active proteins under such conditions.

Furthermore, the requirements of 35 USC 112, first paragraph must be met at the time application was filed. Guo was published almost four and a half years after the effective filing date of the instant application, and does not reflect what one of skill in the art knew at the time the application was filed. It appears that Guo et al. were the first to recognize that proteins in

general may not be a sensitive to mutation as thought previously, e.g. when the instant application was filed.

Finally, Guo shows a type of trial-and-error experimentation that would be required to determine what amino acids could be changed and to what amino acids they could be changed without inactivating the protein. Guo illustrates that one could not envision the exact amino acid sequences differing from SEQ ID NO: 2 that would be present in a phospholipase B encoded by the claimed nucleic acids.

With respect to the argument about PFAM analysis, it is unclear how this is relevant to the written description issue. The instant phospholipase B has the highest sequence identity with phospholipase C enzymes known when the application was filed, and little or no significant homology with phospholipase B enzymes known at that time. Phospholipase B (EC 3.1.1.5) catalyzes hydrolysis of the carboxylic ester bonds between the glycerol moiety and either of the fatty acid moieties of a phospholipid. It is a carboxylic ester hydrolase (EC 3.1.1 family), not a phosphoesterase as stated in the Berka declaration at the bottom of page 4. Phospholipase C (EC 3.1.4.3) is a phosphoric diester hydrolase or phosphodiesterase (EC 3.1.4 family) and cleaves the phosphate ester bond between the glycerol moiety and the phosphate. (See the Enzyme Commission (EC) web site at www.chem.qmul.ac.uk/iubmb/enzyme/EC3/1/ for classification of esterases.) The instant specification does not suggest that PFAM analysis be used to envision functional polypeptides, much less how it should be used. Page 7, lines 8-30, of the specification simply lists the general types of variations that are preferred, and does not teach which of such variations that could possibly be made "do not significantly affect the folding and/or activity of the protein."

Finally, Applicant states (bottom of page 6) that limiting the literal scope of protection to the sequences of SEQ ID NO: 1 or 2 provides little incentive to Applicant to seek patent protection because there will be homologous genes in nature that are structurally and functionally related. The relevance of this statement to the rejection is unclear. It is pointed out that Applicant could have carried out the type of mutational analysis shown in Guo to obtain information on the amino acids that could or could not be changed without eliminating phospholipase B activity, but chose not to. The specification describes a method of screening using SEQ ID NO: 1 as a hybridization probe to identify other organisms that carried homologous sequences, and to then isolate those sequences, and assays for phospholipase B activity that could be used to determine if those sequences encoded a phospholipase B, but chose not to. Applicant describes a single species readable on the broad genus being claimed, but leaves it to one of skill in the art to identify other members of that genus, and to determine the structural characteristics that make the phospholipase B enzymes encoded by the claimed nucleic acids a phospholipase B. "The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention," see *Regents of the Univ. Calif.* at page 1406.

Claims 100, 102-104, 109-111, 114-115, 117 and 119-124 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid sequence encoding a phospholipase B wherein either the nucleic acid sequence comprises nucleotides 568 to 2045 of SEQ ID NO: 1 or the polypeptide comprises amino acids 20-464 of SEQ ID NO: 2 , does not reasonably provide enablement for any other embodiments lying

outside this scope. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims for the reasons of record applied to claims 71-75, 79-82, 84-86, and 88-95, respectively, in the Office action of 12/7/01.

Applicant's arguments filed 11/26/04 have been fully considered but they are not persuasive. Applicant argues that the specification discloses routine techniques that could used by those in the art for identifying other nucleic acids of the invention, such as nucleic acid hybridization techniques, sequence comparison techniques, and assays for phospholipase B activity. Applicant points to paragraph 6 of the Berka declaration where SEQ ID NO: 2 was used to search protein databases for structurally related sequences. In response, the rejection explained why these disclosures in the specification were inadequate to enable the invention. Furthermore, the enablement requirement dictates that the specification describe how to make the invention, not how to identify species made later by others that are readable on the claims. Whether one can determine whether a species is within the meets and bounds of the claims is a requirement under the second paragraph of §112.

Furthermore, the database records cited on page 6 of the Berka declaration were not provided. It is unclear whether these sequences are from the prior art. It is also unclear whether any of them were shown to or expected to have phospholipase B activity, rather than an undetermined phospholipase activity, which also includes phospholipases A1, A2, C and D.

With regard to man-made variants, page 7, lines 8-30, of the specification simply lists the general types of variations that are preferred, and does not teach which of such variations that could possibly be made "do not significantly affect the folding and/or activity of the protein."

The Neurath reference was not provided with Applicant's reply, and has not been considered. Guo shows a type of trial-and-error experimentation that would be required to determine what amino acids could be changed and to what amino acids they could be changed without inactivating the protein. Guo illustrates that one could not predict the exact amino acid sequences differing from SEQ ID NO: 2 that would be present in a phospholipase B encoded by the claimed nucleic acids. Furthermore, Guo suggest that the large majority of polypeptides having but a few amino acid substitutions would be inactive. The claims permit far more amino acid substitution than described in Guo. The specification at pages 13-14 does not teach what the essential amino acids are, and only suggests trial and error experimentation that one may use to identify such amino acids. A teaching of unguided, trial and error experimentation does not satisfy the enablement requirement.

Applicant argues, relying upon paragraph 7 of the Berka declaration, that by October 1999, one of skill in the art was able to routinely able to screen thousands of mutants citing a number of prior art references (some of which were provided with the declaration). Whether one would have been able to make and screen thousands of mutant polypeptides having one or a few amino acid substitutions in a short period of time is not the issue. Rather, the issue is whether such experimentation is undue.

As set forth in *In re Fisher,* 166 USPQ 18 (CCPA 1970), compliance with 35 USC 112, first paragraph requires:

> that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws; in cases involving unpredictable factors, such as most chemical reactions and

> physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.

The fact that purely trial and error experimentation would be required to reduce the generic invention to practice, and without guidance as to what amino acids could or could not be changed and how, clearly indicates that one cannot predict the performance characteristics of the polypeptide encoded by the claimed nucleic acids by "resort to known scientific laws". By suggesting that one should engage in trial and error experimentation, Applicant is tacitly admitting that the specification does not teach how to make the claimed invention based upon predictable factors. As set forth in *Fisher*, such a specification fails to enable how to make the claimed invention without undue experimentation.

The prior art provided by Applicant in support of this argument (¶ 7 of Berka declaration) shows making one amino acid substitution and testing the protein for activity. At best, this art suggests that substitution of one amino acid at a time may have been routine in the art. In contrast, claim 100, part a) permits substitution of up to 44 amino acids, and part b) permits substitution of up to 147 amino acids. The number of possible amino acid sequences differing from amino acids 20-464 of SEQ ID NO: 2 by up to 44 amino acid substitutions, i.e. at least 90% amino acid sequence identity, can be calculated by the formula provided in the Office action of 12/7/01. The last term of the equation simplifies to the following

$$X^nL!/n!(L-n)!$$

where X is 19 alternate amino acids, n is the number of substitutions, and L is the length of the polypeptide. Using n=44 and L=444, there are at least 2×10^{117} different polypeptides that differ from the recited polypeptide by 44 substitutions (which greatly exceeds the number with 43 or fewer substitutions). This is an underestimate of the number of polypeptides to make and test,

which would include 43 substitutions, 42 substitutions, etc., as well as variations using inserted and deleted amino acids. This number of sequences to make and test exceeds "thousands" by beyond an astronomical degree (the universe is estimated to have only 10^{70}-10^{90} atoms).

Consequently, it would require undue experimentation to make the invention commensurate in scope with the claims because of the high unpredictability (trial and error experimentation is required), the lack of guidance in the specification as to what amino acids could be safely changed, the lack of evidence that the making and testing mutant polypeptides having the degree of substitution permitted by the claims was routinely practiced, and the shear physical impossibility of making even a minute fraction of the possible sequences that meet the structural limitations set forth in the claims.

The declaration under 37 CFR 1.132 filed 11/26/04 is insufficient to overcome the rejection of claims 100, 102-104, 109-111, 114-115, 117 and 119-124 based upon a failure of the specification to comply with the written description and enablement requirements of 35 USC 112, first paragraph as set forth in the last Office action for the reasons set forth above in responses to Applicant's arguments as they rely upon the declaration.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action

after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy J. Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott D. Priebe

Scott D. Priebe
Primary Examiner
Art Unit 1632